



PATENT  
Customer No. 27874  
Attorney Docket No. 29794/04001

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
	)	
Randolph M. Howes	)	Group Art Unit: 1616
	)	
Application No.: 10/050,121	)	Examiner: Frank I. Choi
	)	
Filed: January 18, 2002	)	Attorney Docket No.: 29794/04001
	)	
For: Compositions, Methods and	)	
Apparatuses for Singlet Oxygen	)	
Delivery	)	

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.131**

I, Randolph M. Howes, state that I am the named Applicant of the above-identified application, and am the inventor of the subject matter described and claimed therein. Prior to April 29, 1999, I have completed in this country the invention as described and claimed in the above-identified application as evidenced by the following:

1. On March 27 and 28, 1992, I attended a symposium in Photodynamic Therapy at Santa Barbara, California.
2. On the conference materials that were distributed for the conference I took notes on my ideas for methods of delivering singlet oxygen (" $^1\text{O}_2^*$ ") to a target site.
3. On March 29, 1992, I recorded the following notes:

“RMH

3/29/92

– one could also use  $^1\text{O}_2^*$  in an irrigating system for wound cavities such as emphyemas or peritonitis or a wound surface – this would have both bacteriocidal & tumoricidal activity” (Exhibit 1.)

“– an added advantage of injectable  $^1\text{O}_2^*$  is that there is literally no limit to depth of treatment such as seen with PDT in which the light can penetrate only to 5 mm or where diffusion techniques have to be employed” (Exhibit 2.)

“– one could use endoscopes to place the treating  $^1\text{O}_2^*$  virtually anywhere in the body utilizing the injection technique” (Exhibit 2.)

4. In September 1993, I tested the inventive concept on myself.

5. On September 14, 1993, I recorded the following notes as I tested the invention on myself:

“9/14/93 10PM RMH – lesion 0.5 cm dia

– will inj. keratosis on right shoulder with  $\text{H}_2\text{O}_2$  &  $\text{NaOCl}$  – 0.1 cc each with 25 gauge needle & 1 cc tuberculin syringe

– will use 1% xylocaine with 1:100,000 epi

10:15 PM – inj. with xylocaine

10:25 PM – inj. with  $\text{NaOCl}$  – painful

“ “  $\text{H}_2\text{O}_2$  – turned white

11:30 – still painful but turning black

12:00 MN – looks like early scab” (Exhibit 3.)

6. On September 15, 1993, I recorded the following notes based on observations of the September 14, 1993-injection site:

“9/15/03<sup>1</sup> – injected lesion now black with eschar  
– looks like it killed it  
– will try again  
– will wait longer for local anesth.” (Exhibit 3.)

7. On September 21, 1993, I recorded the following notes based on observations of the September 14, 1993-injection site:

“9/21/02<sup>2</sup> – still not sloughed off but lesion is definitely dead” (Exhibit 3.)

8. On March 15, 1996, I repeated the test of the invention on myself, this time reversing the order of the reactant injections.

9. On March 15, 1996, I recorded the following notes as I repeated the invention on myself:

“RMH – 3/15/96 will repeat injection but will use dermal nevus or keratosis.  
1% xylocaine 1:100,000 epi  
nevus on Left forearm <0.3 cm dia  
– inj. 0.1 cc H<sub>2</sub>O<sub>2</sub> first then NaOCl  
can’t inj. both together – needles too awkward  
– seemed to work better with NaOCl first, then follow with H<sub>2</sub>O<sub>2</sub>” (Exhibit 4.)

10. On March 16, 1996, I recorded the following notes relating to the injection site:

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<sup>1</sup> Note that I incorrectly recorded the date as “9/15/03”. In fact, I recorded the notes on September 15, 1993.

<sup>2</sup> Note that I incorrectly recorded the date as “9/21/02”. In fact, I recorded the notes on September 21, 1993.

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“3/16/96 11AM – did do as well as with H<sub>2</sub>O<sub>2</sub> first but did turn black, like with  
PDT” (Exhibit 4.)

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Date: \_\_\_\_\_

\_\_\_\_\_  
Dr. Randolph M. Howes

*Application No. 10/051,121*

*Attorney Docket No. 29794/04001*

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"RMH

3/29/92

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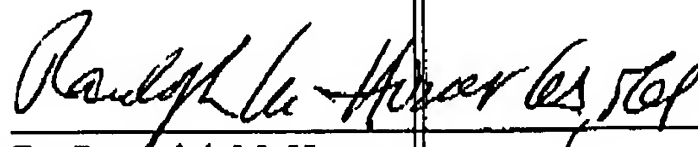
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Date: 11/21/04

  
Dr. Randolph M. Howes

part

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hole

7/24/92

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REDACTED

REDACTED

REDACTED

REDACTED



3/29/92  
— an added advantage of injectable  $O_2^+$  is  
that there is literally no limit to depth  
of treatment such as seen with PDT, in  
which the light can penetrate only to 5 mm,  
or where diffusion techniques have to be employed

REDACTED

REDACTED

REDACTED

8/3/92 3/29/92 — in flight  
— one would use endoscopes to place the treating  
 $O_2^+$  virtually anywhere in the body utilizing the  
injection technique

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REDACTED

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REDACTED

REDACTED

9/18/93 10PM Post - lesion 0.5 cm dia  
- with ag. Keratosis in R shoulder & the L  
Nodule - 0.5 cm each & 25 mg weight  
Ice treated spritz  
- with urea 12% glycama & 18,000 g/d  
10<sup>00</sup> PM - ag. & glycama  
10<sup>20</sup> PM - ag. & Nodule - painful  
" " the L - firm white  
11<sup>30</sup> - still painful but twy black  
1200 AM - looks like early scab

9/19/03 - injected lesion now black & eschar  
- looks like it killed it  
- with try again  
- with wait long for local aneth.

9/21/03 - still not sloughed off but  
lesion is definitely dead

BEST AVAILABLE COPY

REDACTED

1/18/96 with repeat injection but could use  
 several more or less. (20 kg/1000000)  
 Never on ~~5~~ forearm < 0.3 in dia  
 - in 2.1 a block first, then Needle  
 can't get both together - needles to network  
 - seemed to work better - Needle first,  
 then follows the  
 3/14/96 11th - did do as well as 5 block first  
 but did turn black, then E PDT